



Regulation on Advertising of Medicines and Medical Devices

(„Official Gazette of the RS“ no. 79/2010)

Based on the Article 164 Paragraph 9 and Article 204 of the Law on Medicines and Medical devices („Official Gazette of the RS“ no. 30/10) the Minister of Health issued a Regulation on Advertising of Medicines and Medical Devices

(„Official Gazette of the RS“ no. 79/2010, hereinafter: „**Regulation**“) which came into force on November 6, 2011.

This Regulation provides different ways of advertising medicines and medical devices.

Advertising of medicines and medical devices refers to any form of providing accurate information on medical products and medical devices to the general public and professional community in order to encourage medical prescription, supply of medicines and medical devices, their sales and consumption by the holder of the permit for medicine, or the holder of the registration of medical device in the Register of medical devices (hereinafter: “**Register**”).

Advertising of medicines and medical devices includes advertising, promotion, giving free samples to professional community, sponsoring of scientific and promotional events in which participate professional community.

Advertising of medicines must be in compliance with the product characteristics and user manual for medicines approved by the Agency for Medicines and Medical Devices of Serbia, while advertising of medical devices must be in compliance with the user manual. Information on medical product or medical device must be true, scientifically proven and must not mislead the public and professional awareness.

Besides provisions which stipulate that it is forbidden to advertise a drug that does not have permission for the drug, or whose license has expired, as well as medical devices that are not on the Register, or whose decision on registration ceased to have effect, the Regulation also contains directions and prohibitions for the holders of the permit for medicines and holders of the registration of medical devices which they shall respect while advertising medicines and medical devices to the public and professional awareness.

